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Effects of emotion-oriented care on elderly people with cognitive impairment and behavioral problems

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SUMMARY

Objective This study investigates the effects of emotion-oriented care on the behavior of elderly people with cognitive impairment and behavioral problems. This approach is mainly based on the validation approach, but also uses insights from other approaches like reminiscence and sensory stimulation.
Methods 16 Homes for the aged with structured day care units were randomly allocated to an intervention or control group. 151 Residents with cognitive impairment and behavioral problems were included in the study. The eight intervention homes received a training program with regard to emotion-oriented care. In the eight control homes usual care was continued. Measurements were performed at baseline and after 3, 6 and 12 months of follow-up (assessment by caregivers and relatives). The primary outcome measure was the change in behavior of the residents.
Results The results of multilevel analyses (overall, subgroup and per protocol) showed no statistically significant, nor clinically relevant effects in favor of the intervention group on the behavioral outcome measures.
Conclusions There is insufficient evidence yet to justify the implementation of emotion-oriented care on a large scale. Additional studies are needed in which special attention is given to the implementation process. Copyright © 2002 John Wiley & Sons, Ltd.

KEY WORDS — dementia; psychogeriatrics; emotion-oriented care; RCT; multilevel analyses

INTRODUCTION

The aging of the population in western countries has consequences for long term care facilities such as nursing homes and homes for the aged. These facilities will be faced, for instance, with increasing numbers of demented residents with behavior problems. As yet, no effective cure for these residents is available: emphasis is therefore on providing 'the best care possible'.

Several approaches have been developed in psychogeriatric care. One popular approach to care management of disoriented elderly is so-called 'validation' or 'validation therapy'. Validation has been developed by Feil (Feil, 1967; Feil and Wetzler, 1979; Feil, 1984; Feil, 1985; Feil, 1989; Feil, 1990; Feil, 1992), who described it as a process of communicating, both verbally and nonverbally, with disoriented elderly people by validating and respecting their feelings. Validation, or validation therapy, can be used for moderately to severely disoriented elderly people. It implies to accept the disoriented elderly person as he or she is, be non-judgmental and share feelings that are freely expressed. Disoriented persons are not forced in 'our reality', instead their perception of

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the environment is validated. According to Feil (1994), validation increases positive affect, decreases negative affect, stimulates communication and restores well-being in disoriented elderly.

Since 1963 validation is more and more used in many institutions in the United States, Canada, Australia and Europe (Feil, 1994). In general, validation is a popular approach among professional caregivers who have a great believe in its effectiveness. In the Netherlands validation is used in 81% of the nursing homes (Kruyver and Kerkstra, 1996).

We conducted a review of the literature on the effectiveness of validation (Schrijnemaekers *et al.*, 1995). We found 16 studies of which seven were unpublished; only three studies were randomized controlled trials (Peoples, 1982; Robb *et al.*, 1986; Toseland *et al.*, 1997). Nearly all studies suffered from serious methodological shortcomings and the results were conflicting. It appeared that the better the methodological quality of the study, the less favorable the outcomes were. From this review it was concluded that there was insufficient evidence yet for the claimed effectiveness of validation and that additional research, using more rigorous methods, was needed.

In the Netherlands there is a tendency to apply validation in combination with other approaches such as sensory-stimulation and reminiscence. This combined approach, mainly based on the validation approach, is called emotion-oriented care (Finnema *et al.*, 1998; Finnema *et al.*, 2000). In a randomized controlled trial (RCT) we studied the effects of emotion-oriented care on elderly people with moderate to severe cognitive impairment and behavioral problems and on professional caregivers in homes for the elderly. In this article we present the results for the elderly people.

METHODS

The study was performed among residents with cognitive and behavioral problems who attended the structured day-care unit in 16 homes for the elderly in the Netherlands (province of Limburg) in the years 1997–1999. After pre-stratification the16 homes were randomly allocated to an intervention or control group and subsequently a selection of the residents was made. The 8 intervention homes received an emotion-oriented care training. In the 8 control homes usual care was continued. Measurements were performed at baseline and after 3, 6 and 12 months of follow-up. The study was approved by the medical ethical committee (IRB approval) of the Maastricht University Hospital.

Homes for the elderly

Homes for the elderly are residential care facilities with residents with care needs, in terms of physical and mental impairments, that resemble almost those of nursing homes patients. The 16 homes included in the study had not yet implemented an emotion-oriented care approach in the daily care for their residents and had a day-care unit for psycho-geriatric residents. At these care units a structured day-care program is offered to psycho-geriatric residents by occupational therapists and nursing caregivers. The residents involved stay at the day-care unit in the daytime and return to their rooms during the evening.

Pre-stratification and randomization

Randomization was performed on the level of homes. The homes were pre-stratified before randomization on two prognostic characteristics: the capacity of the day-care unit and the degree of care innovation in the homes (presence of resident-oriented care-plans and a system of resident-allocation). On the basis of these two characteristics eight pairs of homes were formed. Next, the homes within each pair were randomly assigned to the intervention or control group.

Participants

Residents had to fulfill the following selection criteria:

- Presence of moderate to severe cognitive impairment and behavioral problems. Cognitive impairment was assessed by means of the standardized Mini Mental State Examination (MMSE) (Folstein *et al.*, 1975; Molloy *et al.*, 1991). The screening interviews were conducted by three trained researchers. Residents with scores below 21 were included in the study (range of scores: 0–30).

  The presence of behavioral problems was assessed by means of a short version of the Dutch Behavioral Rating Scale for Psycho-geriatric Inpatients (Gedragsobservatieschaal voor de Intramurale Psychogeriatrie (GIP-28) (Verstraten and van Eekelen, 1987; de Jonghe *et al.* 1997). This scale was completed independently by caregivers of the structured day-care program and caregivers of the ward where the residents lived. Residents with scores of 30 or more were included in the study (range of scores: 24–96).

- Written informed consent, obtained by a legal representative of the resident (usually a daughter or son).

- Participation in a structured day-care program for at least five half-days a week and residence in the home for the elderly for at least two months before the start of the study.
- Not bedridden, sufficient hearing functions, absence of an unstable psychiatric disorder (except dementia), presence of an adequate level of premorbid intellectual capacity, and absence of expected loss to follow-up from the study during the first six months.

According to a conservative ($1-\beta = 90\%$, $\alpha = 5\%$ (two-sided)) sample size calculation, 60 persons per group were needed to detect a clinical relevant effect on the behavior of the residents (a difference of 10 points on the average score of the GIP-28 between the two groups). Taking into account a loss to follow-up of about 25% during the one year follow-up, 80 residents were needed in each study group.

Intervention

The experimental intervention (intervention homes) was compared to usual care (control homes). The intervention offered to the eight intervention homes consisted of three successive elements: clinical lessons, a training program, and supervision meetings, spread over a total period of eight months. All three elements of the intervention were organized and given by the same qualified and experienced teacher of a professional training organization.

Clinical lessons. Every intervention home first received two identical lessons of approximately one hour. These lessons were offered to all employees (e.g. receptionist, domestic staff, nurses) and aimed at informing employees about the study and the general ideas behind emotion-oriented care.

Training program. Eight caregivers ('students') in each intervention home received a training program in emotion-oriented care. These students had to be key figures in the daily care for residents with cognitive impairment and behavioral problems and had to be able to implement the emotion-oriented care approach in their home. In addition they had to meet the following inclusion criteria: (1) work for at least half a year in the home for the elderly; (2) being employed for at least 18 hours a week; (3) work for at least one year in geriatric care; and (4) have at least a secondary vocational training. On average five caregivers from the day-care unit and three from the wards were selected for the training. The students received a six-day training program. The first four days were given at intervals of two weeks and the last two training days had an interval of four weeks. The training was organized 'in company'.

The training program had various goals. First, participants were taught on the dementia syndrome and various care models for communicating with demented elderly (e.g. Validation, Reminiscence, sensory stimulation). Furthermore, much attention was paid to the inequality of the resident-caregiver relation, the importance of going deeply into and trying to understand the residents' perception of the environment, and the attitude towards and verbal and nonverbal communication with the resident (including the use of sensory perceptions like touch, smell, vision, hearing). Finally, the implementation of practical skills received much attention. Various didactic methods, such as teaching, homework, class assignments and exercises, role-playing and video-presentations, were used during the training.

Supervision meetings. Three supervision meetings (half-a-day each) were offered to support the implementation of emotion-oriented care in daily care. These meetings were again offered in-company over a period of four months after the training was finished. The meetings were 'tailor-made' for every intervention home. Depending on the bottlenecks mentioned by the participants in the first supervision meeting, goals, agreements and evaluations were discussed with those involved.

The eight control homes continued their usual care. To increase the willingness to participate, the control homes were promised to receive the training program after the end of the study.

Outcome measures and timing of measurements

The *primary outcome measure* was the behavior of the residents. We used parts of the Dutch Behavior Observation Scale for Psycho-geriatric Inpatients (Gedragsobservatieschaal voor de Intramurale Psychogeriatrie (GIP)) (Verstraten and van Eekelen, 1987). The GIP is a psycho-geriatric behavior observation scale for institutionalized elderly people. The scale contains 82 items divided over 14 sub-scales[1]

[1]The 14 sub-scales of the GIP are: nonsocial behavior (8 items), apathetic behavior (6 items), distorted consciousness (7 items), loss of decorum (5 items), rebellious behavior (5 items), incoherent behavior (5 items), distorted memory (7 items), disoriented behavior (5 items), senseless repetitive behavior (5 items), restless behavior (5 items), suspicious behavior (7 items), melancholic or sorrowful behavior (6 items), dependent behavior (5 items) and anxious behavior (6 items).

Table 1. Overview of outcome measures used (including sources) for the 151 residents in 16 homes for the elderly

Outcome measures	Theoretical range[a]	Measurement occasions in months	Sources[b]
Primary outcome measures			
Behavior (GIP):[c]		0, 3, 6, 12	U + W
nonsocial behavior	0–24		
apathetic behavior	0–18		
loss of decorum	0–15		
rebellious behavior	0–15		
restless behavior	0–15		
dependent behavior	0–15		
anxious behavior	0–18		
Secondary outcome measures			
Behavior (GIP-28)[c]	0–84	0, 3, 6, 12	U + W + R
Communication (GRGS)	0–7	0, 3, 6, 12	U + W
Agitation (CMAI-D):		0, 3, 6, 12	U + W
verbal aggression	0–30		
aggression	0–36		
physical non-aggression	0–36		
Resident-specific approach	0–4	3, 6, 12	U + W + R
Functional status (ADL)	0–12	0, 3, 6, 12	U + W
Global assessment functioning	0–4	3, 6, 12	U + W + R
Change in psychotropic drug use	0–2	3, 6, 12	W
Nursing home admission and mortalit	not applicable	3, 6, 12	S

[a]The underlined scores indicate the most favorable score for each scale/question.
[b]U: Caregiver(s) day-care **U**nit, W: Caregiver(s) **W**ard, R: **R**epresentative of the Resident, S: **S**taff.
[c]The GIP items were scored by two caregivers from the day-care unit (U) and two caregivers of the ward (W).

that can be used separately. For every item the observer has to rate the frequency of the behavior during the last 2 weeks on a 4-point scale. For our study 7 of the 14 sub-scales were selected, namely: nonsocial behavior, apathetic behavior, loss of decorum, rebellious behavior, restless behavior, dependent behavior and anxious behavior. The validity and reliability of the GIP is adequate to good (Verstraten and van Eekelen, 1987: Verstraten, 1988a; Verstraten, 1988b; de Jonghe *et al.*, 1994; de Jonghe *et al.*, 1996; de Jonghe *et al.*, 1997).

Secondary outcome measures were some other behavior measures, namely a short version of the GIP, called GIP-28 (Verstraten and van Eekelen, 1987; de Jonghe *et al.*, 1997), communication, measured by means of 7 items (30 to 34, 40, 41) of the Geriatric Residents Goal Scale (GRGS) (Cornbleth, 1978; Dröes, 1991), three syndromes of agitation, measured with the CMAI(-D) (Cohen Mansfield Agitation Inventory (Dutch version)) (Cohen Mansfield, 1986; de Jonghe and Kat, 1996), the change in frequency of three resident-specific disturbing behaviors listed at baseline (0 = improvement/4 = deterioration), functional status, measured by means of an Activities of Daily Living (ADL) scale (Schrijnemaekers and Haveman, 1993), a global assessment of functioning on a 5-point scale (0 = very improved/4 = very deteriorated), change in psychotropic drug use (0 = decrease, 1 = the same, 2 = increase) and number of nursing home admissions and mortality.

The primary and secondary outcome measures were measured at various time points and often information about a specific outcome measure was collected from several sources. The timing and sources of the measurements are presented in Table 1.

Staff received oral and written information about the use of the scales. The same staff rated the same resident throughout the follow-up.

The assessment of the primary outcomes by the caregivers of the day-care unit after 12 months was considered as the key outcome in our study. These caregivers are most closely involved in the daily care for the study participants and because it takes some time to implement a new care approach, the possible effects are most likely to occur after 12 months.

Data management and analysis

Handling of missing data. Missing values on items that were a part of a scale or sub-scale were replaced according to the 'mean value of valid sub-tests' principle, i.e. replacement by the mean value calculated from the valid item scores of the scale obtained for the same subject at the same measurement time

point. This replacement strategy was only used if less than 25% of the items of a scale were missing. Missing values on 'single' items were not replaced.

Data analysis. In view of the hierarchical structure of the data (measurement occasions nested within caregivers, who are nested within homes for the elderly), resulting in dependencies between measurements, multilevel analysis was used for analyzing the data (Bryk and Raudenbush, 1992; Snijders and Bosker, 1999). This technique not only accommodates dependencies, but also handles missing data in an adequate way (all available data are included in the analysis and rather lenient assumptions are made regarding the nature of missing data) (Snijders and Bosker, 1999). Ordinal outcome measures were analyzed according to a multilevel ordered logit model. All other outcome measures were analyzed with a linear multilevel model, which is apt for continuous outcome measures. Both types of analyses were performed using the MLwiN program (Rasbash *et al.*, 1999).

Assuming a linear trend for the outcome measures across time, we compared the (unadjusted and adjusted) rate of change (deterioration in most cases) across the two groups. Covariates in the adjusted analyses were the following baseline characteristics: psychotropic drug use, cognitive impairment (MMSE) and age. In addition, the effects of the intervention at short (3 months), medium (6 months) and long term intervals (12 months) were tested. In the latter analyses, no specific relations were assumed between the outcome measure and time of measurement.

In these 'overall' analyses differences between intervention and control homes were tested without considering potential effect modifiers. Therefore additional subgroup analyses were performed. These analyses aim at studying potential modifiers of the effects of emotion-oriented care, based on three characteristics measured at baseline: psychotropic drug use, cognitive impairment and age. All statistical analyses were carried out following the 'intention-to-treat' principle. In addition, per protocol analyses were performed to examine the effect of the intervention as a function of the success of its implementation. These additional analyses were restricted to the primary outcomes measures as obtained from the caregivers of the day-care unit. To conduct these analyses we asked the teacher of the course to give an overall judgment of the success of the implementation of emotion-oriented care (good, moderate or poor) for each of the eight intervention homes. The teacher was blinded with respect to outcomes. The teacher rated three homes good, three moderate and two poor. In the per protocol analyses, the control homes ($n = 8$) were compared to intervention homes with a good implementation ($n = 3$), and to intervention homes with a moderate to poor implementation ($n = 5$).

RESULTS

The residents were recruited from 228 residents who attended the day-care units in the 16 homes for the elderly. After pre-selection 38 residents were excluded, mainly because of transfer to another housing facility (in particular to a nursing home) in short-term. Subsequently, the legal representatives of the remaining 190 residents were asked for a written informed consent of which 20 refused. The remaining 170 residents were screened on cognitive and behavioral impairment. Eleven residents were excluded because their cognitive impairment was only mild. From the remaining 159 residents, eight dropped out just before the start of the intervention (four persons died and four moved to a nursing home). Finally, 151 residents were included and the homes were randomized: 77 residents in the intervention homes and 74 in the control homes.

Ninety per cent of the study population was female and the average age was 85 years. The residents had already lived on average for 3.5 years in the homes and participated on average 12 daily periods (mornings, afternoons or evenings) per week in the day-care program. Table 2 shows that the intervention and control group were to a large extent comparable at baseline. As far as small differences were present these were accounted for in the analyses.

The response and loss to follow-up over time per study group is presented in Table 3. The response rates are equal for the intervention and control groups at the various time points. The cumulative mortality rate in the total population was 6%, 14% and 27% after 3, 6 and 12 months respectively. There were no differences in mortality between the two groups. The cumulative rates of loss to follow-up caused by nursing home admission were 1%, 4% and 9% after the 3, 6 and 12 months respectively. These rates also showed no differences between the intervention and control groups.

Table 4 presents the unadjusted and adjusted estimated differences per months of the linear trend analyses according to the observations of the caregivers of the day-care units and the caregivers of the wards on the primary and secondary outcome measures. An estimated difference of, for example, +0.02 per

Table 2. Comparison between the intervention ($n = 77$) and control ($n = 74$) group residents on baseline characteristics

Characteristic	Empirical range[a]	Intervention group ($n = 77$)		Control group ($n = 74$)	
Gender: female (n, %)	—	70	(90%)	66	(89%)
Psychotropic drug use: yes (n, %)	—	42	(55%)	42	(57%)
Age (years, sd)	(77–99)	84.3	(5.5)	85.9	(5.6)
Residing in home for the elderly (years, sd)	(0–19)	3.5	(3.4)	3.7	(2.3)
Cognitive impairment (MMSE) (average score, sd)	(0–<u>20</u>)	10.8	(5.1)	11.3	(5.1)
Behavior (7 GIP sub-scales)[b]:					
Nonsocial behavior (average score, sd)	(<u>0</u>–21)	8.2	(4.7)	9.5	(5.3)
Apathetic behavior (average score, sd)	(<u>0</u>–18)	7.5	(3.4)	7.3	(4.0)
Loss of decorum (average score, sd)	(<u>0</u>–13)	3.6	(3.4)	3.8	(3.1)
Rebellious behavior (average score, sd)	(<u>0</u>–11)	4.2	(2.4)	4.5	(2.9)
Restless behavior (average score, sd)	(<u>0</u>–14)	4.8	(2.9)	4.2	(2.8)
Dependent behavior (average score, sd)	(<u>0</u>–15)	6.0	(3.3)	5.8	(3.7)
Anxious behavior (average score, sd)	(<u>0</u>–18)	3.4	(3.8)	3.4	(3.8)

[a]The underlined scores indicate the most favorable score for each scale.
[b]Scores from the day-care unit.
*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

month for nonsocial behavior, assessed by caregivers of the day-care unit, means that the control group deteriorates on average +0.02 points more on nonsocial behavior than the intervention group. Assuming a linear trend, the estimated difference after twelve months (the end of our study) is +0.2 ($= 12*0.02$).

Although many estimated differences are in favor of the intervention group (especially according to the caregivers of the day-care units), the differences are small and not clinically relevant. All differences are also not statistically significant.

Next, separate analyses were performed for the short (3 months), medium (6 months) and long term (12 months) for the same outcome measures and sources as described in Table 4 (see Table 5). These analyses do not assume a specific relationship between the outcome measure and time. Only after 6 months statistically significant differences were found between the two study groups for two outcome measures: anxious behavior (GIP) and physical non-aggressive behavior (CMAI-D). The control group had 1.8 points ($p < 0.05$) more deterioration after 6 months compared to the intervention group on the sub-scale anxious behavior and the control group had 2.3 points ($p < 0.01$) less deterioration after 6 months in comparison with the intervention group on the sub-scale physical non-aggressive behavior.

The average change over time for the three time points (3, 6 and 12 months) on the primary outcome measures (7 GIP scales) assessed by the caregivers of the day-care unit are presented in Figure 1. These graphs show that the deterioration is somewhat less for the intervention group on 5 GIP scales (loss of decorum, nonsocial, apathetic, dependent and anxious behavior) over the period of one year. However, only one assessment (anxious behavior after six months) is, as mentioned earlier, statistically significant.

Table 3. Numbers (percentages) response and loss-to-follow-up for the measurements at the day-care unit per group (I = Intervention ($n = 77$), C = Control ($n = 74$))

Measurement	Response		Loss-to-follow-up					
			Cumulative mortality		Cumulative nursing home admission		Other[a]	
	I	C	I	C	I	C	I	C
Baseline	77 (100)	74 (100)	—	—	—	—	—	—
3 months	69 (90)	69 (93)	5 (6)	4 (5)	1 (1)	—	2 (3)	1 (1)
6 months	61 (79)	59 (80)	10 (13)	11 (15)	3 (4)	3 (4)	2 (3)	2 (3)
12 months	48 (62)	45 (61)	21 (27)	20 (27)	7 (9)	6 (8)	2 (3)	2 (3)

[a]Residents no longer participating at the day-care unit or admitted to long-term hospital care.

Table 4. Unadjusted and adjusted estimated differences between the intervention and control group on the primary and secondary outcome measures according to the caregivers of the residents (linear trend multilevel analyses)

Outcome measures	Estimated differences per months in linear trend analyses[a]			
	Caregivers of day-care unit about residents		Caregivers of ward about residents	
	Unadjusted	Adjusted	Unadjusted	Adjusted
Behavior (GIP):				
nonsocial behavior	+0.02	+0.04	+0.05	+0.05
apathetic behavior	+0.08	+0.09	−0.02	−0.01
loss of decorum	+0.01	+0.01	−0.00	−0.00
rebellious behavior	+0.02	+0.02	+0.07	+0.07
restless behavior	+0.05	+0.05	−0.07	−0.07
dependent behavior	+0.03	+0.03	+0.06	+0.06
anxious behavior	+0.08	+0.08	+0.02	+0.03
Behavior (GIP-28)	+0.10	+0.12	+0.06	+0.07
Communication (GRGS)	−0.03	−0.02	−0.00	−0.00
Agitation (CMAI-D):				
verbal aggression	+0.04	+0.04	−0.14	−0.14
aggression	+0.03	+0.04	−0.13	−0.13
physical non-aggression	+0.03	+0.03	−0.14	−0.14
Resident-specific approach:				
First disturbing behavior	+0.01	+0.01	+0.01	+0.01
second disturbing behavior	+0.00	+0.00	+0.00	+0.00
third disturbing behavior	+0.00	+0.00	−0.01	−0.01
Functional status (ADL)	[b]	[b]	−0.00	+0.00
Global assessment functioning	−0.00	−0.00	−0.00	−0.00
Change in psychotropic drug use	[c]	[c]	−0.00	−0.00

[a]The estimated difference is the difference in deterioration per month between the control and intervention group.
A positive difference implies a higher deterioration in the control group.
[b]Excluded because of too many remaining missing values after substitution (many ADL activities are not performed at the day-care unit).
[c]Only measured at the ward.
*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

With respect to the observations of the representatives of the residents, restricted to three outcome measures, the same unadjusted and adjusted linear trend analyses as well as analyses per time period (3, 6 and 12 months) were performed. These results also showed only small and no statistically significant differences between the study groups (see Table 6).

The subgroup analyses showed no statistically significant results. The effect of the intervention apparently does not depend on the age of the resident, the degree of cognitive impairment and psychotropic drug use at baseline.

Finally, per protocol analyses (overall and subgroup) were conducted for the primary outcomes as measured by the caregivers of the day-care unit. In these analyses, the control homes ($n = 8$) were compared to intervention homes with a good implementation ($n = 3$), and to intervention homes with a moderate to poor implementation ($n = 5$).

Only for the analyses for the short, medium and long term separately, three statistically significant results were found after 6 months and one after twelve months. The intervention homes with a moderate to poor implementation showed less deterioration after 6 months compared to the control homes on the sub-scales nonsocial behavior ($p < 0.01$) and anxious behavior ($p < 0.05$). The control homes had a lower (= better) score after 6 months in comparison with the intervention homes with a good implementation on the sub-scale rebellious behavior ($p < 0.05$). The intervention homes with a good implementation scored better on anxious behavior after 12 months of follow-up ($p < 0.05$).

DISCUSSION

One of the aims of emotion-oriented care is to reduce problem behavior in elderly people with moderate to severe cognitive impairment. We were unable to confirm this presumed beneficial effect. The various behavioral outcome measures showed no statistically significant nor clinically relevant results in favor of the intervention group. These results were consistent for all analyses that were performed (overall,

Table 5. Estimated differences between the intervention and control group on the primary and secondary outcome measures according to the caregivers of the residents (multilevel analyses per time period)

Outcome measures	Estimated differences per time period					
	Caregivers of day-care unit about residents			Caregivers of ward about residents		
	After 3 months	After 6 months	After 12 months	After 3 months	After 6 months	After 12 months
Behavior (GIP):						
nonsocial behavior	+0.35	+0.84	+0.08	+1.96	+1.78	+1.01
apathetic behavior	+0.52	+0.81	+0.94	−0.19	−0.30	−0.22
loss of decorum	+0.47	+0.38	+0.18	+0.05	+0.05	−0.10
rebellious behavior	+0.36	−0.35	+0.21	+0.78	+0.78	+0.80
restless behavior	−0.25	+0.26	+0.37	−0.06	−0.42	−0.79
dependent behavior	+0.31	+0.79	+0.24	+0.59	+0.71	+0.84
anxious behavior	+0.81	+1.77*	+0.87	−0.85	+044	−0.02
Behavior (GIP-28)	+1.13	+1.44	+0.77	+1.33	+1.52	+0.90
Communication (GRGS)	−0.06	−0.21	−0.27	−0.37	−0.34	− 0.06
Agitation (CMAI-D):						
verbal aggression	+1.54	+0.78	+0.41	−0.07	−1.10	−1.41
Aggression	+0.59	+0.12	+0.67	−0.87	−0.83	−1.18
physical non-aggression	+0.70	−0.85	+0.97	−0.28	−2.26**	−1.27
Resident-specific approach:						
first disturbing behavior	−0.10	−0.04	−0.05	−0.12	−0.10	−0.04
second disturbing behavior	−0.10	−0.10	−0.01	−0.12	−0.09	+0.03
third disturbing behavior	−0.05	−0.12	+0.06	−0.01	+0.08	+0.11
Functional status (ADL)	[b]	[b]	[b]	+0.21	−0.08	+ 0.12
Global assessment functioning	−0.03	−0.01	+0.03	+0.03	+0.09	+0.03
Change in psychotropic drug use	[c]	[c]	[c]	+0.00	+0.07	+0.02

[a]The estimated difference is the difference in deterioration after 3, 6 and 12 month between the control and intervention group. A positive difference implies a higher deterioration in the control group.
[b]Excluded because of too many remaining missing values after substitution (many ADL activities are not performed at the day-care unit).
[c]Only measured at the ward.
*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

subgroup and per protocol) and for the different sources (caregivers day-care units and wards and representatives of the resident). The six statistically significant results after 6 and 12 months (only partly in favor of the intervention homes), which were probably due to chance (multiple-testing), do not alter these overall findings.

Several explanations for these findings can be considered. One may be that emotion-oriented care has no effect on the behavior of residents in homes for the elderly with moderate to severe cognitive impairment and behavioral problems. Other reasons may relate to various sources of bias and choices in the design and conduct of our study. We will therefore discuss the *adequacy* and *comparability* of the study population, outcome measures and intervention.

Adequacy

The study population in our study consisted of 151 residents in homes for the elderly with moderate to severe cognitive impairment and behavioral problems. This target population was in accordance with the target population for emotion-oriented care approaches.

The outcome measures used assess the most important characteristics of interest (problem behavior) and were the most sensitive, reliable and valid scales available in Dutch versions.

The relatively intensive intervention (two clinical lessons, a six-day training for eight caregivers and three supervision meetings) was organized and given by a qualified and motivated teacher. An evaluation at the end of the six-day training showed that the participants were (very) positive about the training and the teacher. The absence-rate at the training was (only) 9%, of which almost half (4%) was caused by illness.

Comparability

To enhance the comparability of our two study groups, the homes were pre-stratified and randomized at the level of the homes. A comparison of various baseline characteristics showed hardly any differences between the two groups. Nevertheless, adjusted

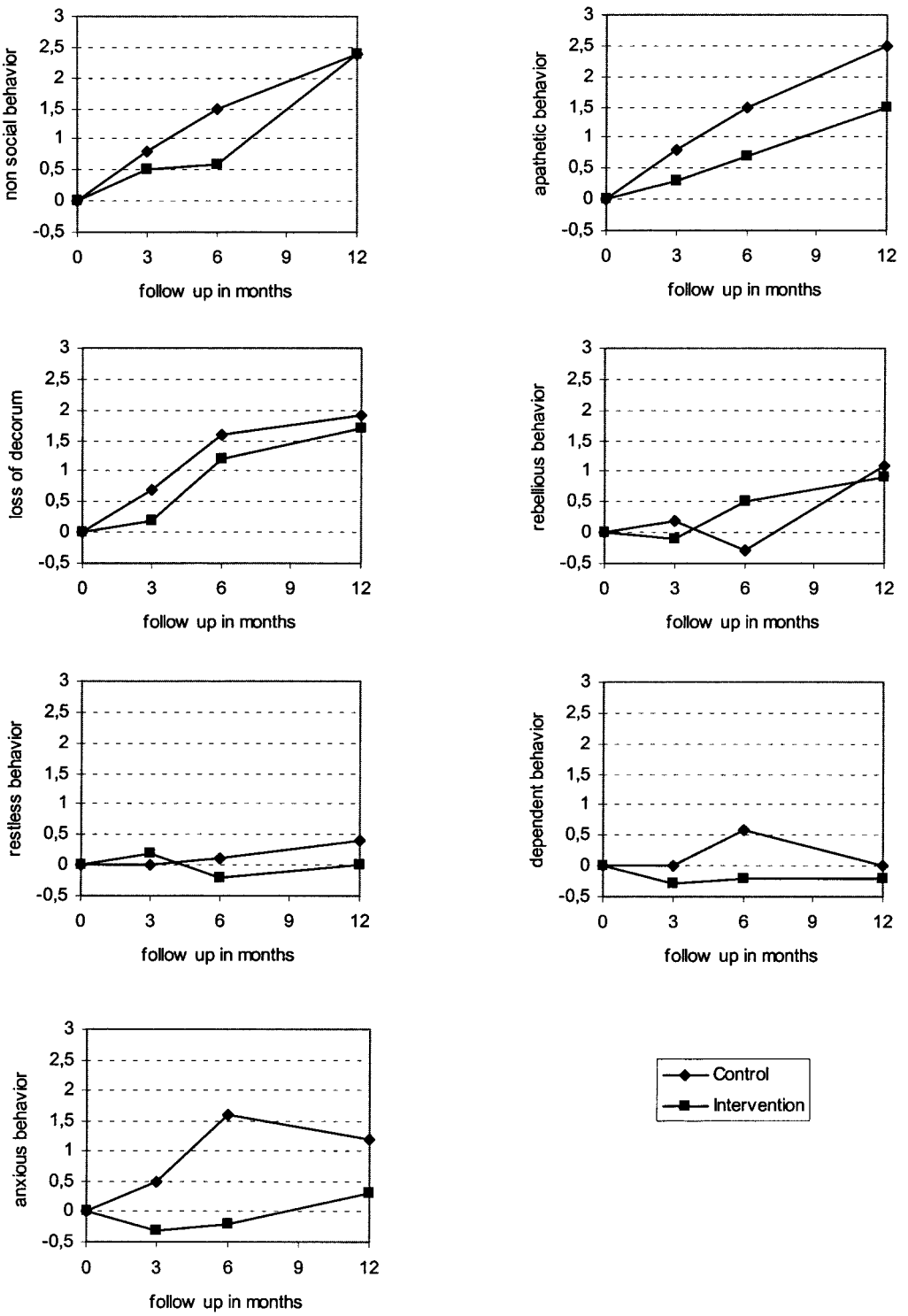

Figure 1. The average deterioration and/or improvement on the primary outcome measures (7 GIP scales) according to the caregivers of the day-care unit for different time point

Table 6. Estimated differences between the intervention and control group according to the representatives of the residents (linear trend multilevel analyses and multilevel analyses per time period)

Outcome measures	Analyses linear trend[a]		Analyses per time period[b]		
	Estimated difference per month[c]		Estimated difference after 3 months[c]	Estimated difference after 6 months[c]	Estimated difference after 12 months[c]
	Unadjusted	Adjusted			
Behavior (GIP-28)	−0.07	−0.07	−0.04	−1.42	−0.52
Resident-specific approach:					
first disturbing behavior	+0.00	−0.00	+0.06	+0.03	+0.04
second disturbing behavior	−0.01	+0.01	+0.05	+0.12	+0.06
third disturbing behavior	−0.00	+0.00	+0.04	+0.01	+0.03
Global assessment functioning	+0.00	+0.01	−0.01	−0.01	−0.24

[a]The estimated difference is the difference in deterioration or improvement per month between the control and intervention group.
[b]The estimated difference is the difference in deterioration or improvement after 3, 6 and 12 months between the control and intervention group.
[c]Positive difference implies a better score for the intervention group.
*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

analyses were performed to control for small differences. Also the loss to follow-up during the one-year period was equally distributed over the study groups.

To assess the outcome measures for the residents we used three sources: caregivers of the day-care unit, caregivers of the ward and representatives of the residents. They were, from different perspectives, capable of assessing the behavior of the residents. Blinded observations were not possible. However, because non-blinded observations usually lead to an overestimation of effects, this does not explain the absence of an effect in our study.

The intervention in our trial was far more intensive than the usual training programs caregivers receive in homes for the elderly. Nevertheless, it is still possible that the intervention did not result in enough contrast between the study groups. On the one hand it is possible that the control homes already use the emotion-oriented care approach 'spontaneously' (contamination), and on the other hand the implementation may not have been optimal in the intervention homes.

To obtain some insight into the implementation of emotion-oriented care, a qualitative study (observations and interviews) was additionally performed. The observations (one day at the day-care unit in four intervention and four control homes), eleven months after the baseline measurement, showed that the emotion-oriented care seemed not (yet) very well observable in the homes. Besides, no clear differences in communication and interaction with the residents between the intervention homes and control homes became visible. Interviews with management and caregivers (12 months after the start of the study) in half of the intervention homes indicated that there may be many (mainly organizational) bottlenecks which can hinder the implementation of the intervention (van Heusden *et al.*, 1999). It appears to be 'hard work' to implement new care approaches 'home-wide'.

On the other hand, no clear effects were found in our per protocol analyses, where intervention homes with a successful implementation were compared to the control homes. Given the foregoing, it is not likely that possible (organizational) bottlenecks were of overriding importance for the absence of effects in our study.

Our results on the behavior of residents are to a large extent consistent with other quantitative studies on the effectiveness of validation or emotion-oriented care approaches. Among the many studies conducted on the effectiveness of validation (Schrijnemaekers *et al.*, 1995) there are only three randomized controlled studies (Peoples, 1982; Robb *et al.*, 1986; Toseland *et al.*, 1997). The methodologically best performed study with larger study groups was that of Toseland *et al.* (1997). They compared nursing home residents who were assigned to a validation group ($n = 31$), a social contact group ($n = 29$) and a control group ($n = 28$) in the USA. The results of this study provided limited support for the effectiveness of group validation for nursing home residents with dementia. Although the nursing staff reported some reduction on agitated behavior, the non-participant observers did not confirm these reductions. There were no significant effects on all the other outcome measures such as psychological functioning, positive behavior, medication and use of physical restraints.

Approximately simultaneously with our study, another study started on the effectiveness of emotion-oriented care in nursing homes (Finnema *et al.*, 1998; Finnema, 2000). Finnema (2000) studied the effects (cognitive, emotional and social adaptation) of emotion-oriented care on demented residents ($n = 146$) in nursing homes in the Netherlands. All 16 selected wards in nursing homes first received a basic training to meet the conditions for quality of care of the Dutch Association for Nursing Home Care. Next, employees on 8 intervention wards received an extensive training: 230 nurses and many paramedical disciplines received a basic training of two days, 75 caregivers received additionally a 'workers' training of 7 days and 14 participants also received a 10-day consultant training. Besides, there was training on the job for the wards and consultants. The follow-up measurement took place after seven months. The results of this study provide also limited support for the effectiveness of emotion-oriented care. Only for two (small) subgroups statistically significant results were found on one of the 9 outcome measures. So even in case of a more intensive intervention (Finnema, 2000), no substantial reduction in problem behavior could be identified in a well-performed RCT.

In conclusion, our results, and those of the other large scale RCTs (Toseland *et al.*, 1997; Finnema, 2000), do not confirm the presumed beneficial effects of emotion-oriented care on problem behavior in elderly people with cognitive impairment. These findings are in contrast with the general positive opinion in the nursing field regarding approaches like emotion-oriented care or validation. In our opinion, there is insufficient scientific evidence yet to justify the implementation of emotion-oriented care on a large scale. Additional evidence from new studies is needed, in which special attention is given to the optimization of the training and the implementation strategy of emotion-oriented care.

KEY POINTS

- Evaluation of emotion-oriented care (EOC) for residents in homes for the elderly with cognitive impairment and behavioral problems
- Randomized Controlled Trial (RCT) with 151 residents
- No convincing effects were found on the behavior of the residents
- Insufficient evidence yet to justify the implementation of EOC on a large scale.

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